K110943

JUL 22 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 1, 2011
Submitter:	GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. 9900 Innovation Dr. Wauwatosa, WI 53226
Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare, GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC. Phone: 414-721-4214 Fax: 414-918-8275
Device: Trade Name:	GE LOGIQ E9 Diagnostic Ultrasound System
Common/Usual Name:	LOGIQ E9
Classification Names:	Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Product Code:	Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	K092271 GE LOGIQ E9 Diagnostic Ultrasound System K052441 GE LOGIQ 7 Diagnostic Ultrasound System
Device Description:	The LOGIQ E9 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 58 cm wide, 86cm deep and 141 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10-inch LCD touch screen and color 19-inch LCD image display.
Intended Use:	The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).
Technology:	The LOGIQ E9 employs the same fundamental scientific technology as its predicate device(s).
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well

as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The LOGIQ E9 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Final Acceptance testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ E9, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ E9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Dr.
WAUWATOSA WI 53226

JUL 2 2 2011

Re: K110943
Trade/Device Name: LOGIC E9 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: July 18, 2011
Received: July 19, 2001

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the LOGIC E9 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

C1-5-D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy, Ph.D. at (301) 796-6242.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known):

Device Name: LOGIQ E9 Diagnostic Ultrasound System

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic, vascular and neurosurgical).

Prescription Use_X___ AND/OR Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K110943

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 Ultrasound System

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application / Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse[9]	Other [Notes]
Ophthalmic											
Fetal/Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ[2]	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Cardiac Adult	P	P	P	P	P	P	P	P	P	P	
Cardiac Pediatric	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Superficial	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Other[4]	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P	P	P	P	P	
Transrectal	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Transvaginal	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Transurethral											
Intraoperative[8]	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Intraoperative Neurological	P	P	P	P	P	P	P	P	P	P	
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance im aging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[9] Volume navigation
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.
System provides real-time 3D and 4D acquisition when used with special 4D probes

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110943

Diagnostic Ultrasound Indications for Use Form
GE LOGIQ E9 with C1-5-D Transducer

Intended Use: Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application / Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse[9]	Other [Notes]
Ophthalmic											
Fetal/Obstetrics[7]	P	P	P	P	P	P	P	P	P	P	[5,6,9]
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Pediatric	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult											
Cardiac Pediatric											
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	P	P	P	P	P	P	P	P	P	P	[3,5,6,9]
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance im aging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[9] Volume navigation
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD. System provides real-time 3D and 4D acquisition when used with special 4D probes

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